

Informed Consent Was Violated With The Covid Hoax + Genocide Injections | Now They Have Quietly Revoked The Requirement 77 Years After It Was Codified In The Nuremberg Code | The Era Of Informed Consent Is Over



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Rule

Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations

A Rule by the Food and Drug Administration on 12/21/2023



PUBLISHED DOCUMENT

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Final rule.

SUMMARY:

The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations to implement a provision of the 21st Century Cures Act (Cures Act). This final rule allows an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The final rule permits an institutional review board (IRB) to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations.

DOCUMENT DETAILS

Printed version:

[PDF](#)

Publication Date:

12/21/2023

Agencies:

[Department of Health and Human Services](#)
[Food and Drug Administration](#)

Dates:

This rule is effective January 22, 2024.

Effective Date:

01/22/2024

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Rule

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ZeroHedge News | Tyler Durden | ZeroHedge.com

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In a significant blow to patient autonomy, informed consent has been quietly revoked just 77 years after it was codified in the Nuremberg Code.

2023-27935

Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk
Clinical Inves

2023-27935.pdf • 418 KB



On the 21st of December 2023, as we were frantically preparing for the festive season, the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) issued a final ruling to amend a provision of the 21st Century Cures Act. This allowed

“... an **exception from the requirement to obtain informed consent** when a clinical investigation poses no more than a minimal risk to the human subject ...”

[They would claim this would apply to the "safe and effective" Covid vaccines]

This ruling went into effect on January 22nd, 2024, which means it's already standard practice across America.

So, what is the 21st Century Cures Act? It is a controversial Law enacted by the 114th United States Congress in January 2016 with strong support from the pharmaceutical industry. The Act was designed to

“... accelerate the discovery, development, and delivery of 21st-century cures, **and for other purposes [?] ...**”

Some of the provisions within this Act make for uncomfortable reading. For example, the Act supported:

- High-risk, high-reward research [Sec. 2036].
- Novel clinical trial designs [Sec. 3021]
- Encouraging vaccine innovation [Sec. 3093].

This Act granted the National Institutes of Health (NIH) legal protection to pursue high-risk, novel vaccine research. **A strong case could be made that these provisions capture all the necessary architecture required for much of the evil that transpired over the past four years.**

Overtaking patient-informed consent was another stated goal of the original Act. Buried under Section 3024 was the provision to develop an “**Informed consent waiver** or alteration for clinical investigation.”

Scholars of medical history understand that the concept of informed consent, something we all take for granted today, is a relatively new phenomenon codified in its modern understanding as one of the critical principles of the Nuremberg Code in 1947. It is inconceivable that just 77 years after Nuremberg, **the door has once again opened for state-sanctioned medical experimentation on potentially uninformed and unwilling citizens.**

According to this amendment, the state alone, acting through the NIH, the FDA, and the Centers for Disease Control and Prevention (CDC), will decide what is considered a “minimal risk” and, most concerning, will determine:

“... appropriate safeguards to protect the rights, safety, and welfare of human subjects.”

Notice the term *subjects*, not patients, persons, individuals, or citizens... but *subjects*. In asymmetrical power relationships such as clinician/patient, it is understood that the passive *subject* will comply with the rulings and mandates of their medical masters. The use of the term *subjects* also serves to dehumanise. The

dehumanisation of populations was a critical component of Nazi human experimentation and, as Hannah Arendt argued, is an essential step toward denying citizens "... the right to have rights."

This ruling also allows researchers and their misguided evangelical billionaire backers to potentially pursue dangerous experimental programs such as Bill Gates' mosquito vaccines, mRNA vaccines in livestock, and vaccines in aerosols. This Act encourages these novel and high-risk programs, with medical studies approved as "minimal risk" by the regulators no longer requiring researchers and pharmaceutical companies to obtain patient consent. Yet, the histories of pharmacology and medicine are plagued with clinical investigations and interventions that were thought to pose no more than minimal risk to humans but went on to cause immeasurable pain, suffering, and death.

This amendment represents merely a first tentative step as the U.S. government *tests the waters* to see what it can get away with. Given the lack of attention this ruling received in both the corporate press and independent media, the government is likely to feel emboldened to widen its scope. Thus, this decision represents the beginning of a chilling revisionism in Western medical history, as patient autonomy is again forsaken.

This ruling, to be actioned by potentially corrupt scientists, health bureaucrats, and captured health and drug regulators, is **another step toward a dystopian future unimaginable just five years ago**. No doubt the infrastructure to implement this decree is already being constructed by the same *groupthink cultists* responsible for the nightmarish pandemic lockdowns, continuing to place the pursuit of profit and *the greater good* above individual choice, bodily autonomy, and informed consent.

Source: Brownstone Institute

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